

**IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

Amen Dhyllon

v.

Alex Michael Azar, II in his official capacity
as the Secretary of Health and Human
Services

No. 20-4593

Civil Action

MEMORANDUM OF LAW

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INTRODUCTION

In this Court’s hands is Plaintiff Amen Dhyllon’s orthodontic career. Guardian Life Insurance reported to the federal government that it terminated his contract. Its false report failed to comply with regulatory requirements. Even so, the report has crippled Dr. Dhyllon’s business and threatens to destroy it. His employer, insurance companies, and patients are aware of the report. He has lost much of his business and faces irreparable reputational, financial, and emotional injury. The report could even destroy his career.

Dr. Dhyllon asked the Secretary to remove the report from the federal database that contains such reports. HHS regulations bound the Secretary to do so for three independently sufficient reasons. The report did not explain in detail the basis for contract termination, explaining only that the company learned adverse “information” about Dr. Dhyllon. In fact, there was no such “information.” And the insurance company provided no due process before contract termination.

Yet the Secretary refused to remove the report. Dr. Dhyllon now challenges that action under the APA. He seeks a preliminary injunction because of the devastating consequences of the report. He will certainly suffer continued irreparable injury. However, most critically, his insurance contracts are up for renewal in early 2021. If the report remains on file, the insurance companies may not renew the contracts he needs to continue his business.

Without a preliminary injunction, the report could destroy Dr. Dhyllon’s business. HHS regulations could deprive him of any monetary remedy for that injury. Accordingly, he asks this Court to require the Secretary to remove the report during the pendency of this litigation.

BACKGROUND

Dr. Dhyllon first explains the administrative process at issue here. He then discusses the dispute before this Court.

A. Health-care companies must report adverse actions to NPDB; the Secretary resolves disputes over reports.

In 1986, Congress enacted the Healthcare Quality Improvement Act. To facilitate “effective professional peer review,” Congress required private companies to report to the federal government certain adverse actions against medical practitioners. 42 U.S.C. § 11101. These reports are then available to the medical community under certain conditions. 45 C.F.R. § 60.18. For instance, hospitals must check for reports when a doctor seeks staff privileges. 42 U.S.C. § 11135(a)(1). These rules apply to dental practitioners. 45 C.F.R. § 60.3.

The National Practitioner Data Bank (“NPDB”) maintains the reports. 45 C.F.R. § 60.1. NPDB makes them available to certain healthcare entities under certain conditions. 45 C.F.R. § 60.18. Healthcare entities rely on NPDB reports in making decisions about providers. In short, NPDB reports have substantial effects on a practitioner’s career.

A practitioner may ask the Secretary to remove or correct a report. 45 C.F.R. § 60.21. If a report is inaccurate, the Secretary must correct it. 45 C.F.R. § 60.21(c)(2)(ii); (Guidebook F-8).¹ If the report does not concern an event reportable to NPDB or if the reporting entity failed to comply with reporting requirements, the Secretary must remove the report. 45 C.F.R. § 60.21(c)(2)(iv); (Guidebook F-5, F-9).

B. Reports of the type at issue here must be accurate, must provide a detailed “narrative description” of what happened, and must be based on some adjudicative process that provided pre-deprivation due process.

Besides the requirement of accuracy of reports, two other legal requirements are relevant to Dr. Dhyllon’s case. In short, for the report to be valid, the insurance company had to: (1) provide Dr. Dhyllon with pre-deprivation due process; and (2) provide in its report a comprehensive narrative

¹ The “Guidebook” is NPDB’s guidance. It is available on NPDB’s website at bit.ly/2F2JY73 (last visited Oct. 5, 2020).

description of the events underlying Guardian’s decision to terminate Dr. Dhyllon’s contract.

Ten different categories of actions are reportable to NPDB. 45 C.F.R. §§ 60.7–60.16. The termination of Dr. Dhyllon’s contract was reportable, if at all, under only a single provision of law: as an “Other adjudicated action[] or decision[]” under § 60.16 (A. 3: Decision).²

The “other adjudicated action” provision stems from 42 U.S.C. § 1320a-7e(a), which requires reports of all “final adverse actions” taken against healthcare practitioners. 42 U.S.C. § 1320a-7e(a). “Final adverse actions” include “Other adjudicated actions or decisions that the Secretary shall establish by regulation.” 42 U.S.C. § 1320a-7e(g)(1)(A)(v). The Secretary defined “Other adjudicated actions or decisions” at 45 C.F.R. § 60.3 and created reporting rules at 45 C.F.R. § 60.16.

The Secretary defined “Other adjudicated actions or decisions” as, relevant here, “formal or official final actions taken against a health care practitioner . . . by a . . . health plan, which include the availability of a due process mechanism, and are based on acts or omissions that affect or could affect the payment, provision, or delivery of a health care item or service.” 45 C.F.R. § 60.3. The definition emphasizes that the “hallmark of any valid adjudicated action or decision is the availability of a due process mechanism.” 45 C.F.R. § 60.3. For private entities such as Guardian, a process that complies with the pre-deprivation notice-and-hearing requirements of 42 U.S.C. § 11112(b) is sufficient. *Id.*

After an “other adjudicated action” is taken adverse to a practitioner, the NPDB specifies how the insurance company must report it to the NPDB. Critical here is that the insurance company must provide “[a] narrative description of the acts or omissions and injuries upon which the reported action was based.” 45 C.F.R. § 60.16(b) (requiring reports to comply with § 60.15(b)); 45 C.F.R.

² The Appendix page numbers refer to the Appendix to Dr. Dhyllon’s Complaint. The Appendix includes what Dr. Dhyllon believes to be the entire administrative record, which was filed under seal as Doc. 6 and provided to this Court’s chambers.

§ 60.15(b)(4)(i). The description must be detailed enough to allow someone to understand what Dr. Dhyllon “is alleged to have done” wrong. (Guidebook E-11).

C. Guardian terminates Dr. Dhyllon’s contract without providing any due process and without explaining what he did wrong.

Dr. Dhyllon had a contract to provide orthodontic services with Guardian Life Insurance (“Guardian”). (A. 2: Decision). On October 9, 2019, Guardian’s Credentialing Committee held a meeting; without objection, it voted to terminate Dr. Dhyllon’s contract. (A. 50: meeting minutes). The meeting minutes do not further explain that decision. (*Id.*).

Guardian did not provide Dr. Dhyllon with any notice of its intent to terminate his contract. It did not provide any pre-termination due process. Instead, the day after termination, Guardian informed Dr. Dhyllon for the first time of the decision that it had already made. (A. 22).

The letter explained: “a review of your records was performed. Guardian detected a questionable pattern of services being performed by your office and upon further investigation, identified a Quality of Care concern. The Quality of [Care] Concern pertains to the current orthodontic investigation. The issue was presented to the Credentialing Committee for review on October 9, 2019, and the Credentialing Committee voted to terminate your Provider Agreement effective October 9, 2019.” (*Id.*).

Despite follow-up letters requesting appeal, Guardian never gave Dr. Dhyllon a hearing. Nor did it give him any opportunity to present evidence. Nor did it ever further explain its decision or what its “concerns” were. Instead, it summarily denied his “appeal.” (A. 8–10, 25–26: correspondence).

D. Guardian submits a report to the NPDB that it terminated Dr. Dhyllon’s contract; its supposed basis was false.

On October 25, 2019, Guardian filed a report with the NPDB explaining that it had terminated

Dr. Dhyllon's contract (the "Report"). (A. 8–10). The Report explains Dr. Dhyllon's alleged wrongdoing in full as follows: "Based on a review of information obtained from our query of the National Practitioner Data Bank and/or the State Dental Board, the credentialing committee voted to terminate, Amen Dhyllon, DDS, from network participation." (A. 9). The Report does not mention the supposed "Quality of Care Concern." Nor does it explain what the supposed adverse "information" was.

In fact, there was no adverse "information" against Dr. Dhyllon on file with either the NPDB or the State Dental Board. Guardian had received printouts from both entities indicating that there were no prior reports against Dr. Dhyllon or any adverse information against him. (A. 54–55).

E. Guardian admits that its report was inaccurate and that it does not know why it terminated Dr. Dhyllon's contract or what he did wrong.

On November 11, 2020, Dr. Dhyllon disputed the report with NPDB *pro se*. (A. 9–10: subject statement). Dr. Dhyllon explained that he did not understand why Guardian had terminated his contract. He explained that he treats patients well and has had excellent results for his patients: "This abrupt termination of the contract has devastated me emotionally and psychologically especially when I don't know what did I do to deserve this abrupt termination. I don't even know what have I done wrong." (*Id.*).

After Dr. Dhyllon filed the initial dispute, he challenged the report through counsel. (A. 17–18). The Division of Practitioner Data Bank ("DPDB") addresses challenges to NPDB reports on the Secretary's behalf. (Guidebook F-4). Counsel submitted two assertions of error:

[a]. The report lacks an adequate "narrative description of the acts or omissions and injuries upon which the reported action was based" as 45 C.F.R.[§§] 60.15(b)(4)(i), 60.16(b) require. The report does not explain the underlying basis for the reporting entity's action, explaining only that it terminated the practitioner from network participation based on unspecified information obtained from the reporting entity['s] "query of the [NPDB]

and/or the State Dental Board.” The practitioner is aware of no prior NPDB or State Dental Board report.

[b]. The reporting entity failed to provide any due process. The termination of network participation is therefore not a reportable event under 45 C.F.R. [§] 60.16. To be reportable, the reporting entity must provide due process.³

(A. 17). Counsel also submitted a supporting legal memorandum and various exhibits. (A. 19–33).

On January 21, 2020, DPDB asked Guardian to explain, within 30 days, why it filed the report and to provide supporting documentation. Guardian responded 64 days late. Despite giving itself two extra months to find any relevant documents, Guardian provided only: (1) the meeting minutes of the initial decision to terminate the contract; (2) printouts establishing that Guardian knew that there was no adverse information from the NPDB or State Dental Board despite its claim that it terminated the contract because of such information; and (3) the correspondence with Dr. Dhyllon already discussed. (A. 49–76). Guardian did not explain why its report inaccurately stated that there were prior adverse reports against Dr. Dhyllon on file with either the NPDB or the State Dental Board.

Dr. Dhyllon’s counsel submitted a letter to DPDB asserting that the Report was inaccurate based on Guardian’s submission. Counsel explained that Guardian failed to present any evidence to show that there was adverse information against him on file with NPDB or the State Dental Board. He requested that the Report be voided for inaccuracy. (A. 81).

DPDB asked Guardian to provide additional documentation “regarding the quality of care concerns” within 20 days. (A. 78–79). Guardian responded 47 days late.

Remarkably, even with the extra time, Guardian explained that *it still did not know the basis for its decision*: “Regarding the supporting documentation for the quality of care concern, I have requested that from the committee; this is not something that is kept for general review. Once

³ The second dispute point also made legal argument about why this issue was within DPDB’s authority to review. The quotation does not include the discussion of that issue.

received, I will provide to the NPDB.” (A. 84). Guardian never provided anything else.

F. The Secretary refuses to remove the report from the NPDB data bank.

DPDB would not remove the report. (A. 5). DPDB ignored the fact that the Report incorrectly claimed that there was adverse information against Dr. Dhyllon in either the NPDB or the State Dental Board’s files. It asserted that this claim was somehow “accurate” without explanation. (A.4). DPDB also explained that it was satisfied with Guardian’s subsequent correspondence explaining that the real problem was not adverse information in these databases, but rather “quality of care concerns.” (A. 4).

While DPDB acknowledged that Guardian had to provide a “detailed narrative describing the acts or omissions of the subject of the report upon which the action is based,” it found that Guardian did so by citing unspecified “quality of care concerns.” (*Id.*). Remarkably, DPDB’s decision did not address Guardian’s admission that it had no idea what those “concerns” were. (A. 84).

DPDB next found that the regulations precluded it from considering whether Guardian provided pre-termination due process. The regulations restrict the grounds on which to challenge a report. Practitioners cannot simply say that what happened to them was wrong. They must identify an inaccuracy in the report or show that the report did not comply with the reporting requirements. *See* 45 C.F.R. § 60.21(c); (Guidebook F-5, F-8).

To that end, NPDB regulations explain that practitioners generally cannot complain of the due process that they were afforded. 45 C.F.R. § 60.21(c). For instance, where a state medical board revokes a doctor’s license, doctors have due-process rights. *United States v. Martinez*, 905 F.2d 709, 713 (3d Cir. 1990) (citing *Beauchamp v. De Abadia*, 779 F.2d 773, 775 (1st Cir. 1985)). Section 60.21(c) prevents the doctor from collaterally challenging the process or substance of the medical board’s decision as a basis to remove a report.

DPDB relied on this provision to preclude any analysis of whether Dr. Dhyllon received due process. (A. 4). It did so even though the definition of a reportable “adjudicated action” requires due process. It did not address 45 C.F.R. § 60.3’s clear statement that due process is necessary for an “other adjudication action” to be “reportable.”

As an alternative ground for its decision on the due-process issue, DPDB explained that Dr. Dhyllon submitted letters to Guardian asking to “appeal,” which “appeal” Guardian summarily rejected without any process. DPDB believed that a “due process mechanism” was therefore available. (*Id.*). DPDB did not address that 45 C.F.R. § 60.3 requires pre-termination notice and hearing — not post-termination “appeal” without any apparent process at all, much less the opportunity to know the charges, attend a hearing, present evidence, and challenge opposing witnesses.

G. Dr. Dhyllon suffers reputational and financial harm from the inaccurate report.

Dr. Dhyllon has sued the Secretary under the APA, challenging his decision not to remove the Report. He now seeks a preliminary injunction requiring the Secretary to do so during the pendency of this litigation. He does so because of the serious and irreparable injury that the Report is causing. Without preliminary-injunctive relief, the Report may destroy Dr. Dhyllon’s career.

The mere existence of the Report has severely hurt his business. While the Report fails to explain any supposed wrongdoing, companies he works for, peers, and insurance companies all believe it to be gravely serious. Companies refer far fewer patients to him. Peers will not refer work to him. Insurance companies are investigating him. Insurance companies have told his patients that they should use another orthodontist given the Report’s existence. These problems and the effect of COVID-19 have reduced his business by approximately 50-60%. (Dhyllon Declaration).

Most concerningly, the NPDB report threatens to destroy his business. The vast majority of Dr.

Dhyllon's revenue comes from insurance companies. He needs contractual relationships with them to treat their patients. Most of those contracts expire in March and April of 2021. Given that the insurance companies are auditing him, Dr. Dhyllon believes that there is a substantial risk that the insurance companies will not renew their contracts absent relief from the NPDB report. Without those contracts, Dr. Dhyllon's business would be destroyed. (*Id.*).

Together, the damage to Dr. Dhyllon's career has emotionally devastated him. He does not even understand what he supposedly did wrong. He has had no chance to defend himself. His once sterling reputation is destroyed. He faces the prospect of seeing everything he has worked for go up in smoke for no apparent reason. Especially given the pending decisions about contract renewal, he has no choice but to ask this Court for preliminary injunctive relief. (*Id.*).

JURISDICTION AND VENUE

This Court has federal-question jurisdiction under 28 U.S.C. § 1331 to consider whether the Secretary's refusal to remove the Report was arbitrary and capricious under the Administrative Procedures Act. *E.g. Costa v. Leavitt*, 442 F. Supp. 2d 754 (D. Neb. 2006) (ordering the Secretary to remove an NPDB report under the APA). In addition, the Secretary's decision not to remove the Report from the data bank is reviewable "final agency action." Dr. Dhyllon has taken all necessary steps to request removal of the Report, rendering the Secretary's decision not to do so final. *See Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (noting that action is "final" if it consummates the agency's decision-making process and if it determines a party's rights)

Venue is proper in the Eastern District of Pennsylvania. Dr. Dhyllon resides here and this action does not involve real property, permitting venue under 28 U.S.C. § 1391(e)(1)(C). Further, all of the underlying events related to Dr. Dhyllon's orthodontic practice occurred here, permitting venue under 28 U.S.C. § 1391(e)(1)(B).

QUESTION PRESENTED

1. Should this Court enter a preliminary injunction ordering the Secretary to remove the Report from the data bank during the pendency of this suit? *Suggested answer:* Yes.

STANDARD OF REVIEW

This Court may issue preliminary injunctions under FED. R. Civ. P. 65(a). The moving party must demonstrate:

- (1) the reasonable probability of eventual success in the litigation [that is, the likelihood of success on the merits]; and
- (2) that the movant will be irreparably injured *pendent lite* [during litigation] if relief is not granted.

Reilly v. City of Harrisburg, 858 F.3d 173, 176 (3d Cir. 2017). In addition, while proof of these elements is not required, this Court should also consider when relevant:

- (3) the possibility of harm to other interested persons from the grant or denial of the injunction, and
- (4) the public interest.

Id. This Court should then “balance” the four factors. *Id.*

Further, the standard of review is more demanding because Dr. Dhyllon seeks a mandatory preliminary injunction to change the status quo. While mandatory preliminary injunctions are available, the movant “bears a particularly heavy burden in demonstrating its necessity.” *Ferring Pharma., Inc. v. Watson Pharma, Inc.*, 765 F.3d 205, 219 n.13 (3d Cir. 2014) (citing *Acierno v. New Castle County*, 40 F.3d 645, 653 (3d Cir. 1994)). Accordingly, “a higher standard of showing irreparable harm in the absence of an injunction” applies. *Bennington Foods*, 528 F.3d at 179 (citing *Tom Doherty Assocs., Inc. v. Saban Entmt., Inc.*, 60 F.3d 27, 33–34 (2nd Cir. 1995)). In addition, the Third Circuit recognizes that it is especially important to consider the risk of harm to other interested

parties in considering mandatory preliminary injunctions. *Punnett v. Carter*, 621 F.2d 578, 577–78 (3d Cir. 1980).

ARGUMENT

Dr. Dhyllon reviews the requirements the requirements for the grant of a preliminary injunction, the possibility of harm to other interest persons, and the public interest in turn.

I. Dr. Dhyllon is likely to succeed on the merits for any of three distinct and independently sufficient reasons.

Dr. Dhyllon has three separate, independently sufficient grounds to find that applicable regulations required the Secretary to remove the Report. Each of these grounds alone establishes the requisite “reasonable probability of eventual success in the litigation.” The Secretary’s failure to comply with his duty under his agency’s regulations is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” under 5 U.S.C. § 706(2)(A).

To grant a preliminary injunction, this Court does not have to agree that these grounds are actually correct. Instead, there need be only be a “reasonable chance, or probability, of winning.” *Singer Mgmt. Consultants, Inc. v. Milgram*, 650 F.3d 223, 230 (3d Cir. 2011) (*en banc*); *see In re Revel AC, Inc.*, 802 F.3d 558, 568 (3d Cir. 2015) (describing that standard).

A. Both Guardian and the Report failed to explain what Dr. Dhyllon supposedly did wrong.

The Report alleges only that Guardian received “information” from the NPDB or from the State Dental Board that justified contract termination—which was false per (A. 54–55). The Report’s bare assertion of unspecified “information” is not a sufficient description of what occurred to allow the Report to remain in the NPDB.

45 C.F.R. § 60.16(b) requires reports of “Other adjudicated actions or decisions” to comply with

§ 60.15(b). Section 60.15(b) requires “[a] narrative description of the acts or omissions and injuries upon which the reported action was based.” 45 C.F.R. § 60.15(b)(4)(i). The “narrative description” must include detailed factual description of what happened:

For each report submitted to the NPDB, reporting entities are required to specify the action taken and include a **detailed narrative** describing the acts or omissions of the subject of the report upon which the action is based. . . .

The narrative description must include **sufficient detail to ensure that future queriers have a clear understanding of what the subject of the report is alleged to have done and the nature of and reasons for the event upon which the report is based.** . . .

Narrative descriptions should be limited to statements of fact and should:

- **Summarize the official findings or state the facts of the case**
- **Include a description of the circumstances that led to the action taken**

(Guidebook E-11) (emphasis added).

Guardian grossly failed to meet those requirements. The Report itself explains only that Guardian terminated Dr. Dhyllon’s contract “[b]ased on a review of information obtained from our query of the National Practitioner Data Bank and/or the State Dental Board.” (A. 9). The Report did not explain what this information was, nor was it even sure what database contained it. A bare recitation that unspecified “information” exists is not a detailed narrative explanation that provides a “clear understanding of what the subject of the report is alleged to have done.”

Guardian’s subsequent explanation that the real problem was supposed “quality of care concerns” is irrelevant. The Report itself must provide the requisite narrative description. 45 C.F.R. § 60.15(b)(4)(i). The report said nothing about “quality of care concerns.”

In addition, the bare assertion of “concerns” is also grossly inadequate. Guardian never explained what the “concerns” were. Instead, it admitted that it had *no idea what the “concerns”*

were despite the Secretary’s demand for that information. (A. 84).

Even *Guardian* does not know the basis for its decision. Nobody else could either. There are no facts, description, or detail to support the supposed “concerns.” A bare assertion that “concerns” exist does not enable anyone to “have a clear understanding of what the subject of the report is alleged to have done and the nature of and reasons for the event upon which the report is based” as page E-11 of the Guidebook requires.

Accordingly, both the Report itself and *Guardian*’s subsequent explanation of its decision failed to comply with 45 C.F.R. § 60.15(b)(4)(i) and so the Secretary should have removed the Report under 45 C.F.R. § 60.21(c)(2)(iv). NPDB guidance requires the Secretary to remove a report whenever it failed to comply with reporting requirements. (Guidebook F-9).

The only case available on Westlaw considering the “narrative description” requirement finds that a report was inadequate in strikingly similar circumstances. In *Costa v. Leavitt*, 442 F. Supp. 2d 754 (D. Neb. 2006), a doctor sought to renew clinical privileges. Hospital staff voted to recommend to the hospital board that it deny the request. The doctor resigned before the board could implement that recommendation. The hospital reported the doctor’s resignation to NPDB.

Ultimately, after finding much of the staff’s issues with the doctor legally irrelevant, the question before the district court was whether a portion of the report provided an adequate narrative description of events. The report’s relevant portion explained that medical staff had “concerns regarding [the doctor’s] professionalism to nursing and administrative staff.” The record showed that the relevant “concern” was that the doctor had allegedly failed to supervise his physician’s assistant, allowing the assistant to perform work beyond the authority of a physician’s assistant.

The district court found that the report did not contain an adequate narrative description, and so ordered the Secretary to remove it. The narrative description was “insufficient.” Merely reciting the existence of unspecified “concerns regarding [the doctor’s] professionalism to nursing and

administrative staff” was not enough. It did not meet the requirements of the NPDB Guidebook discussed at length above.

Costa is strongly persuasive authority supporting Dr. Dhyllon’s position. Both *Costa* and this case involve bare assertions of “concerns.” However, in *Costa*, the hospital was at least able to explain those concerns during the DPDB proceeding. Here, Guardian could not even do that despite having more than eight months to review its records. Dr. Dhyllon should not suffer profound damage to his career when not even Guardian can explain what he supposedly did wrong.

B. Guardian failed to provide any due process.

Dr. Dhyllon first explains why Guardian failed to provide the due process necessary to render his contract termination reportable to NPDB. Then he addresses the Decision’s position that the provision of due process is irrelevant.

i. Dr. Dhyllon’s conviction in absentia in a secret meeting of a committee that cannot explain the charges that it adjudicated or the basis for its decision failed to provide due process.

By definition, something is a reportable “Other adjudicated action or decision” only if it is “adjudicated” with due process:

Other adjudicated actions or decisions means formal or official final actions taken against a health care practitioner . . . by a . . . health plan, **which include the availability of a due process mechanism**, and are based on acts or omissions that affect or could affect the payment, provision, or delivery of a health care item or service. . . . A hallmark of any valid adjudicated action or decision is the availability of a due process mechanism . . . **For health plans that are not government entities, an action taken following adequate notice and the opportunity for a hearing that meets the standards of due process set out in section 412(b) of the HCQIA (42 U.S.C. 11112(b)) also would qualify as a reportable action under this definition.**

45 C.F.R. § 60.3 (emphasis added).

To simplify, because Guardian is a non-governmental “health plan[],” its termination of Dr. Dhyllon’s contract was reportable if Guardian complied with the due-process standard of 42 U.S.C. § 11112(b). Section 11112(b) requires comprehensive, pre-deprivation process, including: notice prior to taking action against a provider with an explanation of the basis for the proposed action, a right to a hearing, notice of the hearing, the right to counsel, the right to present witnesses and evidence, the right to cross examination, the right to a disinterested decisionmaker, and the right to submit post-hearing briefing. 42 U.S.C. § 11112(b).

Guardian did not provide pre-deprivation process in accordance with either 45 C.F.R. § 60.3 or 42 U.S.C. § 11112(b). It provided no pre-deprivation process whatsoever, much less the comprehensive process that § 11112(b) demands. Dr. Dhyllon does not even know what the charges against him are. Much less did he have the chance to rebut them. Remarkably, not even *Guardian* knows the basis for its decision. All Guardian knows is that Dr. Dhyllon is guilty—somehow.

Such grossly unfair proceedings do not provide due process. Dr. Dhyllon should not suffer the profoundly damaging effects of an NPDB report in these circumstances. He is not raising some technical challenge. Instead, the process was so deficient that nobody could tell the Secretary what this dispute is about. It

Because Guardian failed to provide due process, its contract termination was not “reportable” under 45 C.F.R. § 60.3. The Secretary was bound to remove the Report from the NPDB. *See* 45 C.F.R. § 60.21(c)(2)(iv) (“[I]f the Secretary . . . [d]etermines that the adverse action was not reportable . . . the Secretary will . . . direct the NPDB to void the report.”); *see, e.g., Simpkins v. Shalala*, 999 F. Supp. 106, 115–16 (D.D.C. 1998) (ordering the Secretary to remove a report because no reportable event occurred, although under a different category of NPDB report).

ii. **This Court should not defer to DPDB’s decision that the provision of due process is irrelevant.**

DPDB incorrectly concluded that 45 C.F.R. § 60.21(c) prevented it from considering whether Dr. Dhyllon received pre-termination due process. That section outlines the grounds for relief from an improper report to NPDB. It explains that parties can get relief from reports only if they are inaccurate or if they do not comply with reporting requirements. Section 60.21(c)(1) limits other grounds for relief. It states that, in considering a challenge to a report, the Secretary “will not consider the merits or appropriateness of the action or the due process that the subject received.” DPDB believed that this section precluded Dr. Dhyllon’s due-process argument despite 45 C.F.R. § 60.3’s requirement that “other adjudications actions” are reportable only with due process.

In reviewing that decision, this Court should not give any deference to DPDB’s legal reasoning. An agency may be entitled to deference for its interpretation of its regulations under the deference principles of *Auer v. Robbins*, 519 U.S. 452 (1997) and *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945). However, the Supreme Court recently limited *Auer* deference in *Kisor v. Wilkie*, 588 U.S. __, 139 S. Ct. 2400 (2019). An agency’s interpretation of its regulations is entitled to deference only if the interpretation reflects the agency’s “authoritative” position or its “official position.” *Id.* at 2416. While the agency head need not make the decision, the decision must somehow have “emanate[d]” from the agency head or his senior advisers. *Id.*

Here, HHS has not decided how § 60.3 and § 60.21 interact in cases involving “Other adjudicated actions or decisions.” NPDB’s formal guidance, the Guidebook, does not address this question. Instead, all we have is the Decision that Carolyn Nganga-Good, the Chief of the Policy and Disputes Branch of DPDB, signed. The Decision never explicitly addressed the interaction between these two regulations. Nor does it reflect a policy decision about that question “emanating” from the Secretary, but rather that of a subordinate many layers below the Secretary. The Decision’s legal reasoning is thus not entitled to deference under *Kisor*.

Looking to the merits of DBDB's legal reasoning *de novo*, the Decision's refusal to address due process is improper. The definition of "other adjudicated action" directly states that such an action is "*reportable*" only with due process. 45 C.F.R. § 60.3 (emphasis added). At the same time, § 60.21(c) directs the Secretary to remove any action that is not "*reportable*." Therefore, the Secretary must remove a report of an "other adjudicated action" if the subject did not receive due process. If parties cannot challenge whether an "other adjudicated action" meets the definition of that term in § 60.3, the definition is meaningless surplusage. This Court should not so interpret § 60.3.

Any interpretation of § 60.21(c)(1) to preclude review of whether the subject received the due process that § 60.3 requires for a report of an "other adjudicated action" is incorrect. DPDB misunderstood the effect of § 60.21(c)(1). With all other types of NPDB reports, there must have been an opportunity for an adjudicative process *before* a reportable action occurs. The point of § 60.21(c)(1) is to prevent collateral challenges to these adjudicative processes, whether on the merits or because of alleged procedural errors. To illustrate, the section headings of when reports must be made, setting aside "Other adjudicated actions or decisions," are:

- § 60.7 Reporting medical malpractice payments.
- § 60.8 Reporting licensure actions taken by Boards of Medical Examiners.
- § 60.9 Reporting licensure and certification actions taken by states.
- § 60.10 Reporting Federal licensure and certification actions.
- § 60.11 Reporting negative actions or findings taken by peer review organizations or private accreditation entities.
- § 60.12 Reporting adverse actions taken against clinical privileges.
- § 60.13 Reporting Federal or state criminal convictions related to the delivery of a health care item or service.
- § 60.14 Reporting civil judgments related to the delivery of a health care item

or service.

§ 60.15 Reporting exclusions from participation in Federal or state health care programs.

These events all provide for due-process protections for practitioners. For lawsuits (§§ 60.7, 60.14), criminal convictions (§ 60.13), and adverse government actions (§§ 60.8, 60.9, 60.10, 60.15), the constitution requires due process. For private “professional review actions” (§§ 60.11, 60.12), federal law requires due process to gain the benefit of federal immunity from suit for money damages. 42 U.S.C. §§ 11111, 11112(a)(3).

In contrast, “other adjudicated actions” is a catch-all definition for whatever “adjudicated actions or decisions” the Secretary might deem appropriate. 42 U.S.C. § 1320a-7e(g)(1)(A)(v). To ensure that practitioners have the same opportunity for due process that is available for other types of reportable actions, the Secretary limited the scope of reportable “other adjudicated actions” to require adjudication with due process.

Without this limitation, there would be no assurance that the reported action was actually “adjudicated” as Congress demanded. There would be no assurance that practitioners had a fair opportunity to address the allegations underlying a report. The provision of due process is a valid basis to challenge a report of an “other adjudicated action” because the definition requires it.

C. The Report is inaccurate.

The Report states that Guardian terminated Dr. Dhyllon because of adverse information already on file with NPDB or with the State Dental Board. But the administrative record makes clear that no such information exists. (A. 54–55). Accordingly, the report is inaccurate.

The Secretary was thus bound to remove the Report. Under 45 C.F.R. § 60.21(c)(2)(ii), the Secretary must direct that an inaccurate report be “revise[d].” Here, the entire basis for the Report was inaccurate. The only way to “revise” an entirely inaccurate report is to remove it.

II. The Report has caused irreparable harm, which Dr. Dhyllon will continue to suffer unless this Court orders the Secretary to remove it.

To grant a preliminary injunction, it must be “likely” that the movant will suffer irreparable harm. *In re Revel AC, Inc.*, 802 F.3d 558, 569 (3d Cir. 2015). “Likely” means “more apt to occur than not.” *Id.*

Here, the report has already caused profound irreparable injury to Dr. Dhyllon. It has devastated his business and may yet destroy his career. It has already cost him hundreds of thousands of dollars for which he cannot sue the Secretary and which may be completely unrecoverable. It has profoundly damaged his reputation. And it has caused him profound distress to see his career and livelihood threatened when he had no opportunity to even understand the charges against him — much less to defend himself. Each of these harms is irreparable.

Reputational injury. The Report has already profoundly harmed Dr. Dhyllon’s standing in the dental community and in his business. Other orthodontists know about the report. His company knows about the report. They believe that he did something wrong even though he did not and even though the Report does not explain any supposed wrongdoing.

The Third Circuit recognizes that this harm is irreparable. It has noted that “loss of control of reputation, loss of trade, and loss of good will” are all irreparable injuries. *Opticians Ass’n of Am. v. Independent Opticians of Am.*, 920 F.2d 187, 195 (3d Cir. 1990). Subsequent cases explain that these injuries are irreparable because it is almost impossible to financially quantify the resulting injury, and because of the non-compensable harm to consumer perception of the business. *Ferring Pharm., Inc. v. Watson Pharm., Inc.*, 765 F.3d 205, 211 (3d Cir. 2014), *modified on other grounds by Reilly v. City of Harrisburg*, 858 F.3d 173 (3d Cir. 2017).

As a result, the Third Circuit has found damage to a business’s reputation and perception are irreparable injuries in a variety of circumstances. *Ferring Pharm.*, 765 F.3d at 211 (false advertising);

Groupe SEB USA, Inc. v. Eure-Pro Operating LLC, 774 F.3d 192, 206 (3d Cir. 2014) (same); *BP Chemicals, Ltd. v. Formosa Chem. & Fibre Corp.*, 229 F.3d 254, 263 (3d Cir. 2000) (effect of misappropriation of trade secrets on reputation for security); *Opticians Ass 'n*, 920 F.2d at 195 (lost guild membership); *Fitzgerald v. Mountain Laurel Racing, Inc.*, 607 F.2d 589, 601 (3d Cir. 1979) (loss of professional licensure); *Pappan Enters., Inc. v. Hardee's Food Sys., Inc.*, 143 F.3d 800, 806 (3d Cir. 1998) (unauthorized use of service mark); *New York v. U.S. Metals Refining Co.*, 771 F.2d 796, 805 (3d Cir. 1985) (release of state's unproven allegations of pollution).

Financial harm. While financial harm is not typically irreparable, it is here. In considering whether financial harm is irreparable, at least in breach-of-contract cases, the Third Circuit has considered: “(a) the difficulty of proving damages with reasonable certainty, (b) the difficulty of procuring a suitable substitute performance by means of money awarded as damages, and (c) the likelihood that an award of damages could not be collected.” *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 802 (3d Cir. 1989) (citing Restatement (Second) of Contracts § 360 (1981)). The first and third factors, the only ones relevant here, show that Dr. Dhyllon’s financial harm is irreparable.

As to the ascertainability of damages, it would be almost impossible to determine Dr. Dhyllon’s damages. As outlined in the reputational injury section above, the Third Circuit recognizes as much for injuries like the one that Dr. Dhyllon suffered. In addition, COVID-19 has also hurt Dr. Dhyllon’s business. It would be difficult to prove precisely what portion of the harm to his business arises from the report versus the effect of COVID-19 and associated governmental restrictions. Lastly, if Dr. Dhyllon lost his insurance contracts, it would be difficult to determine how much money Dr. Dhyllon would have made had those contracts been renewed.

As to the likelihood of an award of money damages, there is a substantial likelihood that Dr.

Dhyllon could not recover any damages at all from Guardian.⁴ Under 45 C.F.R. § 60.22, Guardian is immune from liability unless it had “actual knowledge of the falsity of the information contained in the report.” The administrative record shows that Guardian’s claim that there was adverse information against Dr. Dhyllon on file with NPDB or the State Dental Board was false. However, if Dr. Dhyllon sued Guardian, showing *actual knowledge* of the falsity of the information would be difficult. Further, Guardian could potentially defend itself by claiming that it made a mistake, and that the real basis for its decision were the unspecified “quality of care concerns.” If that were relevant, which Dr. Dhyllon does not concede, proving that Guardian knew that it did not actually have any such concerns would be, at best, a challenge.

In sum, it is almost impossible to determine what damages Dr. Dhyllon will suffer. Even if he could do that, NPDB regulations may preclude recovery. Under clear Third Circuit precedent, his financial harm is irreparable.

Emotional harm. Dr. Dhyllon faces the loss of his career. He still has no idea why Guardian terminated his contract. He had no chance to defend himself. He has been put through an ordeal that threatens his very livelihood. To say the least, the risk of the destruction of everything Dr. Dhyllon has worked to achieve for no apparent reason has, in his words, “devastated [him] emotionally and psychologically.” (A. 9–10).

This harm is irreparable. As outlined above, the immunity provision of NPDB’s regulations may prevent any monetary recovery. Courts recognize that non-compensable emotional injury can be an irreparable harm. *E.g. Chalk v. U.S. Dist. Court.*, 840 F.2d 701, 709 (9th Cir. 1988) (emotional injury suffered by teacher from transfer to non-teaching position was non-compensable under applicable law and so was an irreparable injury); *see also Adams v. Freedom Forge Corp.*, 204 F.3d

⁴ Dr. Dhyllon may sue Guardian for damages. He does not concede that recovery is unavailable. Instead, he argues only that the law provides a high bar for recovery.

475, 489–90 (3d Cir. 2000) (recognizing that emotional injury could be irreparable, but declining to so find). Dr. Dhyllon should not be forced to watch an unlawful NPDB report destroy his business and suffer the personal toll that causes.

III. Other interested parties, particularly Guardian, would suffer no harm from removal of the Report.

Here, there is only one apparent interested party besides the parties to this suit — Guardian. It would not suffer harm from removal of the Report during the pendency of this litigation.

Guardian no longer has any interest in what happens to the Report. Guardian has terminated Dr. Dhyllon’s contract. This action does not challenge that termination. Dr. Dhyllon is not separately challenging that termination. Dr. Dhyllon and Guardian have no continuing relationship. Accordingly, removing the Report from the NPDB would have no effect on Guardian.

Presumably, the reason that Guardian filed the Report in the first place is that the failure to report an “adverse action” to NPDB can lead to a fine of up to \$25,000. 42 U.S.C. § 1320a-7e(b)(6)(A). Guardian has filed its report and so has protected its interest in avoiding fines. Any interest that Guardian may have had in the Report is moot.

While Dr. Dhyllon could potentially sue Guardian for the Report’s inaccuracies, the grant of a preliminary injunction would have no effect in any such lawsuit. Guardian is not a party to this action, and so no issue-preclusive effect could arise against it. *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 326 (1979) (noting that preclusion applies only against a party to the prior judgment). Moreover, the grant of a preliminary injunction is of course an interlocutory order, and so could never have preclusive effect. *See U.S. ex rel. Doe v. Heart Solution, P.C.*, 923 F.3d 308, 316 (3d Cir. 2019) (outlining the elements of issue preclusion). Instead, only this Court’s final judgment would have any preclusive effect—although not against Guardian.

IV. The public interest in ensuring accurate peer review of medical professionals counsels in favor of removing of the Report.

The public interest at stake here is Congress's decision that mandatory reporting to NPDB would facilitate "effective professional peer review," thereby addressing medical malpractice. 11 U.S.C. § 11101. That interest counsels in favor of removing the Report.

The Report contains factually incorrect information: that there was supposedly prior adverse information against Dr. Dhyllon in either the NPDB or on file with the State Dental Board. This information provides no benefit to the public. It does not facilitate effective peer review.

Instead, the Report's false claims mislead. Insurance companies and peers are relying on the Report despite its falsity. Peer review based on false information cannot possibly serve Congress's intent to facilitate effective professional peer review.

CONCLUSION

Dr. Dhyllon asks this Court to order the Secretary to remove the Report from the NPDB during the pendency of this litigation. He further asks this Court to require the Secretary to notify previous recipients of the Report that it has been removed, per 45 C.F.R. § 60.21(c)(2).

Respectfully submitted,

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